

December 18, 2024

Dear Covered Entity:

In follow-up to our previous communications on August 17, 2020, October 30, 2020, and April 3, 2023, we are providing an update on additional steps that Novartis is taking as part of its 340B Drug Pricing Program. After careful consideration, we have decided to adjust our contract pharmacy policy to more closely match the 340B program's intended focus, while preserving the sustainability of this vital program.

The following policy supersedes any previous policy or exemptions, effective January 1, 2025:

- **Non-grantee covered entities:**
  - These entities may purchase at the 340B price for their in-house pharmacies. In the event the covered entity does not have an in-house pharmacy, Novartis will allow such covered entity to designate one contract pharmacy location where Novartis will ship 340B discounted product. The designated contract pharmacy is required to be a dispensing pharmacy that is not a central fill location.
  - Beginning on January 1, 2025, Novartis will require that all non-grantee covered entities upload their claims data to the 340B ESP™ platform for those contract pharmacies designated as well as certain state-based contract pharmacies also permitted under this policy, to increase transparency, mitigate instances of duplicative discounts, and otherwise help maintain the integrity and sustainability of this vital program.
  - Covered entity owned contract pharmacies do not qualify as in-house pharmacies.
- **Federal grantees:**
  - These entities are exempt from any contract pharmacy or data submission restrictions
  - Novartis reserves the right to terminate contract pharmacy exemptions for federal grantees on a case-by-case basis as appropriate.
- **State exemptions:**
  - Details on state covered entity exemptions to this policy can be found on **Attachment A**, which Novartis may update in its sole discretion.
- Novartis expects that all dispensing to 340B eligible patients of the covered entity through a third-party pharmacy will occur only through product shipped by Novartis or an authorized distributor directly to the eligible pharmacy locations designated under this policy and that consistent with the prohibitions in Section 503(c)(3) of the Federal Food, Drug, and Cosmetic Act, the covered entity, as a hospital or health care entity, must not sell or trade or offer to sell or trade 340B drugs to a third-party pharmacy.

Novartis continues to support the core mission of the 340B program to increase access to outpatient drugs by uninsured, low-income, and other vulnerable patients. For non-grantee covered entities that do not have an in-house pharmacy and seek to designate a contract pharmacy location, please go to <https://www.340besp.com/designations> and complete the online form.

If you have any questions, please contact us at [Novartis.340B@novartis.com](mailto:Novartis.340B@novartis.com).

Sincerely,

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## Frequently Asked Questions

### **Q: What is Novartis' policy for non-grantee covered entities?**

A: For non-grantee covered entities, beginning on January 1, 2025, Novartis will allow covered entities to purchase at the 340B price for their in-house pharmacies.

In the event the non-grantee covered entity does not have an in-house pharmacy, Novartis will allow such covered entity to designate one contract pharmacy location where Novartis will ship 340B discounted product. The designated contract pharmacy is required to be a dispensing pharmacy that is not a central fill location.

Novartis will facilitate bill to/ ship to orders of 340B priced products to the contract pharmacy location only; provided that the non-grantee covered entity submits limited claims data on 340B utilization for such contract pharmacy location.

### **Q: What is Novartis' policy for federal grantee covered entities?**

A: All federal grantee covered entities continue to be exempt from our contract pharmacy policy.

Novartis reserves the right to terminate contract pharmacy exemptions for federal grantees on a case-by-case basis as appropriate.

### **Q: Are there any exemptions to the Novartis policy?**

A: The only exemptions to the policy are federal grantee covered entities, and the state exemptions listed in **Attachment A**, which Novartis may update in its sole discretion.

### **Q: Which Novartis products are subject to this updated contract pharmacy policy?**

A: Novartis' policy and the list of Novartis products subject to the policy can be found on 340B ESP™ [www.340BESP.com](http://www.340BESP.com).

### **Q: Does my non-grantee covered entity have an "in-house pharmacy"?**

A: An "in-house pharmacy" which may be referred to as an "entity-owned pharmacy" is any type of pharmacy, including but not limited to specialty pharmacy, retail pharmacy, etc. that is:

- (i) Owned 100% by your covered entity,
- (ii) Appropriately licensed or authorized by the applicable state,
- (iii) Capable of dispensing Novartis 340B covered outpatient drugs, and
- (iv) Not listed as a contract pharmacy for your covered entity on OPAIS

It does not include a pharmacy partially owned by your non-grantee covered entity, or a pharmacy owned by an entity other than your covered entity, including a parent or affiliated entity other than your covered entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship to address on OPAIS does not confer entity-owned status on the pharmacy.

### **Q: Can child sites also designate a single contract pharmacy?**

A: No. A child site must utilize the parent site's contract pharmacy designation. Novartis considers all sites together as one covered entity, inclusive of the parent and child sites, listed on the HRSA database.

**Q: My non-grantee covered entity has an in-house pharmacy that is capable of purchasing and dispensing Novartis products, but my entity does not use it to dispense Novartis products. Can my entity designate one contract pharmacy instead?**

A: No. If a non-grantee covered entity has an in-house pharmacy capable of purchasing Novartis products at the 340B price and dispensing the medicines to patients, the entity must use that pharmacy and may not designate a contract pharmacy instead.

**Q: What if my non-grantee covered entity does not have an in-house outpatient pharmacy at the location registered as a parent or child site on the 340B covered entity database?**

A: If your non-grantee covered entity does not have an in-house outpatient pharmacy capable of dispensing covered outpatient drugs, your covered entity may designate a single contract pharmacy location. Novartis will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; provided:

- (i) your covered entity registers with 340B ESP™ and completes the attestation, and
- (ii) your covered entity submits limited claims data on 340B utilization for such contract pharmacy (see below for more details)
- (iii) the contract pharmacy is not a central fill pharmacy.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location or more often if the designated contract pharmacy relationship is terminated from the HRSA OP AIS database. Please note that such designations may take up to 10 business days to become effective.

**Q: Can I designate a central fill pharmacy as my contract pharmacy?**

A: No. The designated contract pharmacy is required to be a dispensing pharmacy for patients with prescriptions filled at that pharmacy and is not a central fill location.

**Q: Can my wholly owned contract pharmacy access 340B pricing?**

A: Contract pharmacies that are wholly owned by the non-grantee covered entity (or have common ownership with the entity), including those previously exempted by our policy, will not be able to access 340B pricing unless:

- (i) the covered entity lacks an in-house pharmacy, and
- (ii) the wholly owned pharmacy is not a central fill pharmacy and is designated as the single contract pharmacy through the 340B ESP™ platform.

**Q: Does my non-grantee covered entity need to have a HIN registered for the contract pharmacy that they designate?**

A: Yes, a contract pharmacy must have a HIN assigned to it for a covered entity to designate it as its single contract pharmacy. This information is important for Novartis to manage its process with its wholesalers.

**Q. If the contract pharmacy my non-grantee covered entity wants to designate doesn't have a HIN, how does my entity get one?**

A: Novartis will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to [support@340besp.com](mailto:support@340besp.com).

If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN. If you have previously registered a contract pharmacy without a HIN, 340B ESP™ will notify you if such information needs to be updated. If you have questions, please reach out to [support@340BESP.com](mailto:support@340BESP.com).

**Q: May a non-grantee covered entity designate a single contract pharmacy ‘replenishment’ location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?**

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and location. To ensure transparency and program integrity, Novartis expects all dispensing to eligible patients will occur at the properly designated contract pharmacy location(s), and 340B priced drugs will be shipped directly to that location either by Novartis or an authorized distributor.

**Q: May my non-grantee covered entity tally dispensing activity from non-designated contract pharmacy locations and/ or a non-eligible pharmacy locations and place subsequent orders to be shipped to a different, single designated contract pharmacy or covered entity in-house location?**

A: No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B priced drugs. Covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity.

**Q: My non-grantee covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g., six different pharmacy locations). Can my entity designate all locations of the same pharmacy?**

A: No. Novartis’ policy allows 340B non-grantee covered entities to designate a single contract pharmacy location only. Contract pharmacy locations are registered individually on the HRSA database and covered entities are permitted to designate only a single contract pharmacy location that corresponds to a single contract pharmacy registered with HRSA.

**Q: Is Novartis requiring data for my designated contract pharmacy if my non-grantee covered entity does not have an in-house pharmacy?**

A: Yes. Data is required for a designated contract pharmacy for non-grantee covered entities, unless otherwise indicated in **Attachment A**.

**Q: What are the requirements for submission of claims data?**

A: The claims data submission requirement applies to a non-grantee covered entity without an in-house pharmacy that designates one contract pharmacy. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity’s patient. Please submit claims data within the specified period to ensure your designated contract pharmacy location remains eligible to receive 340B priced products. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced products.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at [www.340BESP.com](http://www.340BESP.com) for additional details on



submitting claims data, including the limited set of required data fields. Please refer to **Attachment A** for state level requirements where applicable.

**Q: How will Novartis use the 340B claims data that covered entities provide through 340B ESP™?**

A: Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates (such as in Medicaid) determine compliance with Novartis' 340B integrity initiative and determine eligibility for placing certain replenishment orders under the policy.

**Q: My non-grantee covered entity already designated a single contract pharmacy location without submitting claims. Does my entity need to take action?**

A: Covered entities do not need to make a new designation but will need to start submitting claims data starting January 1, 2025.

Covered entities that need to make a new single contract pharmacy designation will need to do so by Saturday, December 21, 2024 to be eligible by January 1, 2025. Covered entities that do not make a designation by December 21, 2024 will take up to 10 business days to be eligible.

To get started with the 340B ESP™ platform, follow these three simple steps:

1. Go to [www.340BESP.com](http://www.340BESP.com) to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP™ and submit your 340B contract pharmacy claims data twice monthly. Once your account is set up, the claims upload process takes about 5 minutes.

**Q: What happens if non-grantee covered entity does not provide 340B limited claims data?**

A: If a non-grantee covered entity does not submit the requested 340B limited claims data required by Novartis policy, the covered entity may lose the ability to access 340B pricing at the designated contract pharmacy location. To ensure non-grantee covered entities have time to establish an internal claims submission process, we will allow non-grantee covered entities to have 60 days after the effective date of this policy to begin submitting data. After March 1, 2025, if a non-grantee covered entity does not submit claims data, the non-grantee covered entity may not be able to access 340B pricing at the designated contract pharmacy location. Claims must be submitted within 45 days of date of dispense to the patient.

If you need any support with complying with this claims data submission, please reach out to [support@340BESP.com](mailto:support@340BESP.com) for any assistance related to the claims submission process and/or the ESP portal.

## Attachment A

To ensure compliance with the state-imposed requirements under Arkansas Act 1103, Mississippi SB 2145, Minnesota HF 4991, Louisiana Act 348, Maryland HB 1056, we have decided to adjust our 340B Contract Pharmacy Policy for covered entities and their contract pharmacies, as set forth below.

**Arkansas:** Beginning March 20, 2024, Arkansas hospital covered entities will be able to order products and/or place “Bill to/Ship to” replenishment orders with respect to Arkansas-based community pharmacies with which they have contract pharmacy arrangements.

**Maryland:** Beginning, September 16, 2024, Maryland hospital covered entities will be able to order products and/or place “Bill to/Ship to” replenishment orders with respect to Maryland based pharmacies with which they have contract pharmacy arrangements provided they upload their claims data to the 340B ESP™ platform for those contract pharmacies designated pursuant to this updated policy. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ must submit claims data to continue with access to 340B pricing at their contract pharmacies. Novartis reserves all rights in connection with this issue.

**Mississippi:** Beginning July 8, 2024, Mississippi hospital covered entities will be able to order products and/or place “Bill to/Ship to” replenishment orders with respect to Mississippi based pharmacies with which they have contract pharmacy arrangements provided they upload their claims data to the 340B ESP™ platform for each contract pharmacy. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ must submit claims data to continue with access to 340B pricing at their contract pharmacies. Novartis reserves all rights in connection with this issue.

**Minnesota:** Beginning August 1, 2024, Minnesota hospital covered entities will be able to order products and/or place “Bill to/Ship to” replenishment orders with respect to Minnesota based pharmacies with which they have contract pharmacy arrangements provided they upload their claims data to the 340B ESP™ platform for those contract pharmacies designated pursuant to this updated policy. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ must submit claims data to continue with access to 340B pricing at their contract pharmacies. Novartis reserves all rights in connection with this issue.

**Louisiana:** Beginning October 4, 2024, Louisiana hospital covered entities will be able to order products and/or place “Bill to/Ship to” replenishment orders of physical product at the 340B price for products dispensed as of October 4, 2024, with respect to Louisiana based pharmacies with which they have contract pharmacy arrangements provided they upload their claims data to the 340B ESP™ platform for those contract pharmacies designated pursuant to this updated policy. Covered Entities that currently have a contract pharmacy designation in place through 340B ESP™ must submit claims data to continue with access to 340B pricing at their contract pharmacies. Novartis reserves all rights in connection with this issue.